

# EXHIBIT 5

To  
Memorandum In Support of TriPath Imaging, Inc.'s Motion to Exclude  
Defenses Based on Cytoc's CDS-1000

Civil Action No. 03-11142 [DPW] - Lead Case

Filed May 5, 2005

2379	COMPLETE AND RETURN APPLICATION BY	1 JUN	1996	OMB No. 0925-0001
Department of Health and Human Services Public Health Service		ZRG7	Review Group SSS-3 (22)	Type 5
			Activity R44	Grant Number CA63970-03
<b>Application for Continuation Grant</b>		Total Project Period		
		From: 09/30/95 Through: 07/31/97		
		Requested Budget Period		
		From: 08/01/96 Through: 07/31/97		

To be verified by applicant. Check information in items 1 through 6. If incorrect, furnish correct information in item 13.

1. TITLE OF PROJECT AUTOMATED PAP TEST SCREENING FOR QUALITY CONTROL		4. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) CYTYC CORPORATION 237 CEDAR HILL STREET MARLBOROUGH, MA 01752	
2. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) ZAHNISER, DAVID J CYTYC CORPORATION 237 CEDAR HILL STREET MARLBOROUGH, MA 01752		5. ENTITY IDENTIFICATION NUMBER 1020407755A1	
2b. E-MAIL ADDRESS david.zahniser@cytyc.com		6. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL PRESIDENT CYTYC CORPORATION 237 CEDAR HILL STREET MARLBOROUGH, MA 01752	
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT ---		E-MAIL ADDRESS	
2d. MAJOR SUBDIVISION ---			
3. ORGANIZATIONAL CODE 70			

Complete the following (see instructions).

7. HUMAN SUBJECTS <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		7a. If "Yes," Exemption no: 4 or IRB approval date		7b. Assurance of compliance no.		8. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		8a. If "Yes," IACUC approval date		8b. Animal welfare assurance no.	
9. COSTS REQUESTED FOR NEXT BUDGET PERIOD 9a. DIRECT \$ 286,788 9b. TOTAL \$ 377,508		10. INVENTIONS AND PATENTS (See instructions) <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If "Yes," <input type="checkbox"/> Previously reported <input type="checkbox"/> Not previously reported		11. PERFORMANCE SITE(S) (Organizations and addresses) Cytyc Corp (see address above)  New England Medical Center Dept. of Pathology 750 Washington St. Boston, MA 02111		12a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) David J. Zahniser		AREA CODE 508 508		TELEPHONE NO. AND FAX NO. 481-1341 481-2173 fax	
		12b. NAME OF ADMINISTRATIVE OFFICIAL (Item 6) Patrick Sullivan						same			
		12c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 15) Patrick Sullivan President						same			
		E-MAIL ADDRESS									

13. USE THIS SPACE FOR CORRECTIONS TO ITEMS 1 THROUGH 6. INDICATE THE NUMBERS(S) WHERE ANSWERS APPLY.

14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PI / PD NAMED IN 2a (In ink. "Per" signature not acceptable.) David J. Zahniser		DATE 5/11/96	
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 12c (In ink. "Per" signature not acceptable.) Patrick Sullivan		DATE 5/11/96	

DETAILED BUDGET FOR NEXT BUDGET PERIOD—DIRECT COSTS ONLY		FROM 8/01/96	THROUGH 7/31/97	GRANT NUMBER CA63970-03		
PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT			SALARY REQUESTED	FRINGE BENEFITS	TOTALS
David J. Zahniser	Principal Investigator	12	20	23,000	5,750	28,750
Kathy Mui	Cytotechnologist	12	40	24,800	6,200	31,000
Kam Lin Wong	Image Analyst	12	100	74,000	18,500	92,500
Steven Meuse	Sr. Software Eng.	12	50	34,500	8,625	43,125
Norman Soule	Lab technologist	12	50	16,500	4,125	20,625
SUBTOTALS →				172,800	43,200	216,000
CONSULTANT COSTS Dr. Martha Hutchinson (24 days @\$1,000), Louise Isenstein (24 days @\$600), Gary Gill (6 days @\$1,000)						44,400
EQUIPMENT (Itemize)  Dual Power Macintosh Processor with monitor, 80 meg memory, and frame grabber						15,288
SUPPLIES (Itemize by category)  Filters, 5,000 @ \$1.75 8750 Stains/reagents 450 Disks/tapes 400 Video print paper 500						10,100
TRAVEL One trip for principal investigator						1,000
PATIENT CARE COSTS		INPATIENT				
		OUTPATIENT				
ALTERATIONS AND RENOVATIONS (Itemize by category)						
OTHER EXPENSES (Itemize by category)						
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD				\$ 286,788		
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS				
		INDIRECT COSTS				
TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD (Item 7a, Face Page) →				\$ 286,788		

CONFIDENTIAL  
ATTORNEY'S EYES ONLY

C 0073053

PRINCIPAL INVESTIGATOR: Zahniser, David J.

**ABSTRACT OF RESEARCH PLAN****NAME, ADDRESS, AND TELEPHONE NUMBER OF APPLICANT ORGANIZATION**

Cytoc Corporation  
237 Cedar Hill Street  
Marlborough, MA 01752

**YEAR FIRM FOUNDED**  
1989

**NO. OF EMPLOYEES (Include all affiliates)**  
50

**TITLE OF APPLICATION**

Automated Pap Test Screening for Quality Control

**KEY PROFESSIONAL PERSONNEL ENGAGED ON PROJECT**

NAME	POSITION TITLE	ORGANIZATION
David J. Zahniser	Vice President, Scientific Affairs	Cytoc Corporation
Martha L. Hutchinson	Director, Cytopathology	New England Medical Center
Louise Isenstein	Scientific Systems Analyst	New England Medical Center

**ABSTRACT OF RESEARCH PLAN:** State the application's long-term objectives and specific aims, making reference to the health-relatedness of the project, describe concisely the methodology for achieving these goals, and discuss the potential of the research for technological innovation and commercial application. Avoid summaries of past accomplishments and the use of the first person.

The abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. Since abstracts of funded applications may be published by the Federal Government, do not include proprietary information. DO NOT EXCEED 200 WORDS.

In this research, the primary goal is to develop an automated cervical smear analysis system for use after manual screening of thinlayer cervical specimens as a quality control (QC) instrument. The device will measure nuclear features termed "Malignancy Associated Changes" (MACs) to identify disease in samples that are falsely negative by manual methods. At the current levels of technology and in the present regulatory environment, the development of such a system will play an important role in laboratory quality, and will likely reach the market long before an automated primary screening device. The use of MACs is new and innovative in that it allows fast and accurate processing at a very reasonable system cost. In Phase II a fully automated prototype would be developed and tested. Specific research areas are 1) the optimization of the stain, 2) the use of multiple focal planes, 3) optimization of classifiers, and 4) completion and testing of a completely automated prototype. Specification and design of a commercial instrument will begin at the end of Phase II and continue into Phase III.

Provide key words (8 maximum) to identify the research or technology.

Pap smear, Automation, Quality Control, Malignancy Associated Change

Provide a brief summary of the potential commercial applications of the research.

This device would provide enhanced quality control for Pap test analysis in all cytology laboratories worldwide. The current practice of rescreening 10% of negative smears is not adequate. Implementation of a fast and inexpensive automated system used after manual screening would result in increased accuracy and improved healthcare.